Biotron Limited
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27 October 2023

The Manager Companies
ASX Limited
20 Bridge Street
Sydney NSW 2000 (3 pages by email)

Dear Madam

REPORT ON ACTIVITIES FOR THE QUARTER ENDED 30 SEPTEMBER 2023

Biotron Limited ('Biotron' or 'the Company') has achieved key outcomes including:

- Completed a Phase 2 trial of BIT225 (BIT225-012) for treatment of adults with COVID-19 at sites in Thailand following receipt of approvals from relevant ethics and regulatory authorities.
- Continued detailed post-clinical phase analyses of samples collected during the completed the two Phase 2 trials of BIT225 for treatment of HIV-1 infection (BIT225-010 and BIT225-011).
- Continued the design, synthesis and testing of new compounds with the aim of identifying next-generation lead anti-HIV-1 and anti-SARS-CoV-2 drugs and a lead candidate for HBV.
- Publication of BIT225 data in an animal model of COVID-19 in a peer-reviewed international scientific paper.

SARS-CoV-2/COVID-19 Program

During the quarter ended 30 September 2023, the Company completed a Phase 2 clinical trial (BIT225-012) with its lead antiviral drug BIT225 for treatment of COVID-19 at sites in Thailand.

The trial commenced in May 2023 and was very quickly fully enrolled with dosing completed in August 2023.

The double blind, placebo-controlled trial aims to determine if 7 days of treatment with BIT225 commenced within 3 days of onset of COVID-19 symptoms results in reduction in SARS-CoV-2 blood viral load, clinically favourable changes in viral, inflammatory and immune activation markers, as well as improvement in clinical symptoms of COVID-19.

The design of the trial was based on guidance received during 2022 from the USA Food and Drug Administration (FDA) and took into consideration the continually changing landscape of COVID-19. The Company consulted with international clinicians, clinical research organisations and other relevant experts to design a study aimed at being recruited quickly and generate meaningful data in a tight timeframe.

In addition to its unique clinical activity against HIV- 1, BIT225 has shown very good activity against SARS-CoV-2 and prevented development of disease in a COVID-19 mouse model. As previously announced (ASX announcements 25 November 2021, 17 March 2022 and 2 May 2022) BIT225 demonstrated both antiviral, immune modulatory and clinical benefit against SARS-CoV-2 in an accepted murine model of disease. The SARS-CoV-2-infected mice quickly die from respiratory disease very similar to human COVID-19. However, BIT225 very efficiently reduced levels of SARS-CoV-2 virus and stopped the life- threatening cytokine storm. BIT225-treated mice did not develop any signs of disease and remained healthy throughout the several studies that were conducted. 2

Despite the availability of SARS-CoV-2 vaccines, there remains a need for oral drugs to treat the infection and prevent severe disease, especially in at-risk individuals. BIT225 has an established human safety profile and the potential to be an important first in class drug for COVID-19 treatment.

Laboratory analyses and other end of trial activities including monitoring of all information collected during the trial by an external Contract Research Organisation (CRO) is currently in progress. Once these activities are completed, the trial database will be locked, the data unblinded and statistical analyses of the data can be completed. Release of headline results is expected in coming weeks.

During the quarter, a peer-reviewed paper containing BIT225 COVID-19 mouse data was published in a prestigious scientific journal.

The paper, entitled “Post-infection treatment with the E protein inhibitor BIT225 reduces disease severity and increases survival of K18-hACE2 transgenic mice infected with a lethal dose of SARS-CoV-2” has been published as an open access online article in PLoS Pathogens. The paper, written in collaboration with international scientists in the USA and Denmark, underscores the high efficacy of BIT225 and its potential to treat COVID-19.

HIV-1 Program

During the quarter, work has continued to complete the extensive detailed laboratory analyses of the many thousands of samples collected during the two completed Phase 2 trials (BIT225-010 and BIT225-011) of BIT225 for treatment of HIV-1 infection. These assays are complex, requiring specialised facilities and expertise in a number of laboratories in Australia and overseas.

While all effort is being made to complete this work as efficiently as possible, the assays are precise and time consuming and must be done in accordance with international guidelines for undertaking such studies. Once the assays are completed the extensive data sets will be compiled and statistically evaluated.

The two HIV trials have been designed to generate data that extend the positive findings from previous clinical trials conducted by Biotron in which BIT225 was shown to have positive effects on key immunologic markers of improved health outcomes. The data will be central to demonstrating to potential pharmaceutical partners and regulatory authorities the safety and efficacy of BIT225 in patients with currently unmet medical needs.

Headline results from the two HIV-1 trials are expected in coming weeks.

Hepatitis B Program

While the clinical programs for HIV-1 and COVID-19 continue to be the Company's main focus, the Hepatitis B virus (HBV) program continues to be an important preclinical program.

Biotron is working with other experienced groups to access key antiviral HBV assays and continues to make good progress.The aim is to identify a lead series to progress to preliminary safety studies and assessment in animal models of HBV infection.

The current pandemic highlights the importance of novel approaches such as Biotron's viroporin compounds which have the potential to target a broad range of existing and emerging viruses.

Expenditures

As disclosed in the Company's Quarterly Cash Flow Report, expenditure on these research and development activities during the quarter totaled $1,016,000 and $211,000 of related staff costs. As disclosed in the Company's Quarterly Cash Flow Report, payments to related parties and their associates during the quarter totaled $149,000 for director fees, salaries and superannuation payments.

By order of the Board

Peter J. Nightingale
Company Secretary

pjn11913

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
BIOTRON LIMITED	
ABN	**Quarter ended ("current quarter")**
60 086 399 144	**30 September 2023**

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,016)	(1,016)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(211)	(211)
	(f) administration and corporate costs	(168)	(168)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	32	32
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,363)**	**(1,363)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**-**	**-**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	(10)	(10)
3.10	**Net cash from / (used in) financing activities**	**(10)**	**(10)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,984	3,984
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,363)	(1,363)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(10)	(10)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**2,611**	**2,611**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	71	95
5.2	Call deposits	2,540	3,889
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**2,611**	**3,984**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	149
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

Director fees, salaries and superannuation payments.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**-**	**-**

7.5	**Unused financing facilities available at quarter end**	-

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

	N/A

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,363)
8.2	Cash and cash equivalents at quarter end (item 4.6)	2,611
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	2,611
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.92

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer Yes

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: The Company is progressing its application for an R&D development grant rebate for the Company's eligible research and development expenditure on its antiviral drug development programs during the year 2022/2023. As in previous years, the refund is expected to be in excess of $1.0 million.

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: Yes, supported by funding from the R&D development grant rebate.

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 27 October 2023.

Authorised by: By the Board.
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.